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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,592	02/27/2004	Stig Pedersen-Bjergaard	03-41 US	6822
23693	7590	06/07/2007	EXAMINER	
Varian Inc. Legal Department 3120 Hansen Way D-102 Palo Alto, CA 94304			MUI, CHRISTINE T	
			ART UNIT	PAPER NUMBER
			1709	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/788,592	Applicant(s) PEDERSEN-BJERGAARD ET AL.	
	Examiner Christine T. Mui	Art Unit 1709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 25-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 25-45 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>27 February 2004</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-24, drawn to product, classified in class 436, subclass 178.
  - II. Claims 25-39, drawn to process of use, classified in class 210, subclass 635.
  - III. Claims 40-45, drawn to process of making, classified in class 210, subclass 506.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product.

The product as claimed can be used in a materially different process such as chromatography.

2. Inventions I and III are related as product made and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process

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(MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make a materially different product.

The process claimed can be used to make osmotic distillation membranes and can be used in artificial lungs, plasma separation or water purification.

3. Inventions II and III are directed to related process of use and process of making.

The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The making of product and process of use of product perform distinct functions as claimed such as chromatography and osmotic distillation membrane and use in artificial lungs.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the

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election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

1. During a telephone conversation with Bella Fisherman on 08 May 2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 25-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7-11, 13-19 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/088672 to Varian, Inc. (article submitted in the Information Disclosure Statement (IDS) filed on 27 February 2004, herein referred "Varian, Inc."). Regarding claim 1, the Varian, Inc. reference discloses a hollow fiber comprising of a liquid extraction membrane made from synthetic organic polymers and of a hollow fiber. The hollow fiber encloses an internal cavity separated from a donor sample by the extraction membrane placing a static acceptor liquid in the internal cavity (see page 1, lines 31-33 to page 2, lines 1-5 and page 6, lines 2-3).

As for claim 2, the Varian, Inc. reference discloses the polymeric substrate is a hollow fiber membrane (see page 2, line 6 and page 6, lines 2-3).

As for claim 3, the Varian, Inc. reference discloses the membrane comprises of supports made of cellulose, which is a fatty acid ester (see page 6, lines 28-30). Varian, Inc. also discloses a coating of a polyester, which is interpreted as a fatty acid ester (see page 22, line 6).

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As for claims 4 and 5, the Varian, Inc. reference discloses the membrane coating as a polyester (see page 22, line 3-6), which can obtain the characteristics of having 12-30 carbon atoms in the acryl chain and 1-12 atoms in the ester portion as this is a polymer and able to have many carbon atoms in the chain or in the ester group.

As for claims 7 and 8, the Varian, Inc. reference discloses a membrane is an aryl alkyl ether containing the polar nitro functionality (see page 34, line 25-26) where the alkyl portion of the ether can obtain the characteristics of having 5-30 carbon atoms and the aryl portion of the ether can obtain the characteristics of 5-20 carbon atoms.

As for claim 9, the Varian, Inc. reference discloses where the fibers of the membrane are able to carry the acceptor solution on the lumen side (see page 9, line 33 and page 10, lines 1-2).

As for claims 10 and 11, the Varian, Inc. reference discloses the carrier fibers are made of different polymeric materials, such as polypropylene, polysulfone, polycarbonate or polyether sulfone which are able to isolate a single analyte from a complex mixture or group of analytes (see page 10, lines 13-18). The fibers having ability of separating a single analyte from a mixture or group is characterized as an ionophore, transporting specific ions through a cellular membrane, and an organic ion.

As for claim 13, the Varian, Inc. reference discloses that the fibrous polymeric membrane can be made from polyesters, polyurethanes and functionalized polyolefins (see page 8, line 33 and page 10, line 1).

As for claim 14, the Varian, Inc. reference discloses that the membrane can be made of polyolefins (see page 10, line 1).



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As for claim 15, the Varian, Inc. reference discloses the fibers in the membrane can be made of polypropylene, polysulfone, polycarbonate or polyether sulfone, etc. (see page 10, lines 16-18).

As for claim 18, the Varian, Inc. reference discloses that the aqueous feed solution is on the shell side of the fiber and the organic solvent acceptor solution is on the lumen side with the same solvent forming the supported membrane (see page 12, lines 1-3).

As for claim 19, the reference Varian, Inc. discloses the liquid membrane hollow fiber can be employed in the well plate and autosample vial formats in a static mode that can furnish a high degree of sample enrichment (see page 11, lines 30-32).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc. as applied to claim 3 above, and further in view of USP 3,612,283 to Stricker (herein referred "Stricker").

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Varian, Inc. discloses the claimed invention except for the composition of the membrane made of vegetable oil, specifically soya oil, olive oil or tea tree oil. Stricker teaches that it is known to have membranes that have been impregnated with olive oil (see column 1, lines 51-54). This type of membrane does not permit the passage of substances of an acid character if present in weakly acid to neutral solution. It would have been obvious at the time the invention was made to construct the liquid membrane of olive oil to provide a hydrophobic layer on the membrane as to not be solvated or degraded by the solvent.

7. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc..

The reference Varian, Inc. discloses that hollow fiber membrane can have a lifetime of five days or less and a membrane made of nitrophenyloctyl ether the membrane life can be between 10 and 20 days. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the membrane to last 30, 60 or 90 days, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617.F.2d 272, 205 USPQ 215 (CCPA1980).

8. Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varian, Inc. in view of USP 6,354,443 to Moya (herein referred "Moya").

Regarding claim 20, the reference Varian, Inc. teaches the claimed invention except for the hollow fiber being comprised of a porous polymeric substrate and a liquid membrane. Moya teaches that it is known to construct a porous membrane substrate

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made of a thin polymeric porous or ultrafiltration membrane formed of a polymeric composition (see column 11, lines 11-14). It would have been obvious at the time the invention was made to construct the membrane from porous polymeric substrate as taught by Moya to isolate a particular analyte extracted from a large volume of a sample solution.

As for claim 21, the reference Varian, Inc. discloses the membrane comprises of supports made of cellulose, which is interpreted to be a fatty acid ester (see page 7, line 28-30). Varian, Inc. also discloses a coating of polyester, which is interpreted as a fatty acid ester (see page 22, line 6). Moya teaches that it is known to construct a porous membrane substrate made of a thin polymeric porous or ultrafiltration membrane formed of a polymeric composition (see column 11, lines 11-14). It would have been obvious at the time the invention was made to make the porous polymeric membrane from fatty acid esters to obtain a high enrichment of analyte in the hollow fiber from the donor solution.

As for claim 22, the references Varian, Inc. and Moya teach the claimed invention.

Varian, Inc. teaches that the hollow fiber polymeric membrane can be formed by polymerization of monomers in the pores or by coating the preformed polymers.

Examples of the polymers that can be used are polyesters, polyurethanes and functionalized polyolefins (see page 8, lines 30-33 and page 9, line 1). Moya teaches that it is known to construct the polymer membrane of fluorine –containing polymers (see column 11, lines 29-30). It would have been obvious at the time the invention was

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made to construct the membrane from polymers to obtain a high efficiency of separation of the analyte in the sample solution.

As for claim 23, the reference Varian, Inc. and Moya teaches the claimed invention where the polymeric substrate includes polyolefins such as polyethylene, polypropylene and polymethylpentene (see column 11, lines 25-31). It would have been obvious at the time the invention was made to construct the membrane from polyolefins so that no exposed substrate surface is present and the uniform construction of the membrane is able to promote uniform filtration.

As for claim 24, the references Varian, Inc. and Moya teach the claimed invention.

Varian, Inc. discloses that hollow fiber membrane can have a lifetime of five days or less and a membrane made of nitrophenyloctyl ether the membrane life can be between 10 and 20 days. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the membrane to last 30, 60 or 90 days, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617.F.2d 272, 205 USPQ 215 (CCPA1980).

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim language at the beginning states that the "organic ion is" and at the end of the claim the language denotes "and". It is unclear to the examiner if the organic ions are all of the ions listed or is one from the list of ions.

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 2004/0171169 A1 to Kallury et al; WO 00/33050 to Rasmussen et al.

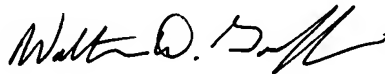
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine T. Mui whose telephone number is (571) 270-3243. The examiner can normally be reached on Monday-Friday 8-5; Alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM



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